

**Docket No.: UPAP0002-100**

**Serial Number: 09/359,975**

**PATENT**

**Filed: July 23, 1999**

### **REMARKS**

#### **Status of the Claims**

Claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, 115-157 are in the application.

Claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, 115-157 were rejected.

By way of this amendment, claims 67-72, 75, 76, 84-86, 94-96 and 126-140 have been canceled and new claims 158-165 have been added.

Upon entry of this amendment, claims 58, 59, 63, 64, 115-125 and 141-165 will be pending.

#### **Summary of the Amendment**

The claims have been amended to more specifically define aspects and embodiments of the invention.

Claims 67-72, 75, 76, 84-86, 94-96 and 126-140 have been canceled without prejudice.

New claims 158-165 have been added to define specific embodiments of the invention. Support for the amendment is found throughout the specification and claims as originally filed. No new matter has been added.

#### **Rejection under 35 U.S.C §112**

Claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, 115-157 stand rejected under 35 U.S.C §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is asserted that the specification does not provide enablement for therapeutically immunizing an animal. It is asserted that undue experimentation would be required to practice the invention.

Claims 67-72, 75, 76, 84-86, 94-96 and 126-140, which are directed at methods of immunizing an individual have been canceled and the rejection is moot as applied to those claims. The remaining claims are in condition for allowance.

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Claims 115-121 and 141-147 are directed at methods of introducing DNA molecules into cells of an individual. The rejection of the claims and the evidence offered in support thereof is directed at making the case that methods of immunizing are unpredictable and that such methods would require undue experimentation. Applicants respectfully point out that the claims 115-121 and 141-147 are directed at methods of introducing DNA molecules and do not require that protective or therapeutic immunity be induced in the individual in order to practice the invention as claimed. None of the evidence is directed at the unpredictability of methods of introducing DNA molecules into an individual. Those having ordinary skill in the art would accept the objective truth of Applicants' assertion in view of totality of the evidence.

Claims 148-157 and new claims 158-165 are directed at methods of inducing antibodies against an antigen in an individual. The rejection of the claims and the evidence offered in support thereof is directed at making the case that methods of immunizing are unpredictable and that such methods would require undue experimentation. Applicants respectfully point out that the claims 148-157 and new claims 158-165 are directed at methods of inducing antibodies and do not require that protective or therapeutic immunity be induced in the individual in order to practice the invention as claimed. None of the evidence is directed at the unpredictability of methods of inducing antibodies against an antigen into an individual. Those having ordinary skill in the art would accept the objective truth of Applicants' assertion in view of totality of the evidence.

Claims 58, 59, 63, 64 and 122-125 are directed at compositions useful for introducing DNA molecules into cells of individuals and for inducing antibodies against antigens in individuals. Nothing in claims 58, 59, 63, 64 and 122-125 require that protective or therapeutic immunity be induced in the individual in order to practice the invention as claimed. Those having ordinary skill in the art would accept the objective truth of Applicants' assertion in view of totality of the evidence.

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**Non-statutory Double Patenting**

Various claims have been rejected over the judicially created doctrine of obvious-type double patenting as being unpatentable over various claims in U.S. Patent Nos. 5,981,505, 5,817,637, 5,830,876 and 5,593,972. At this time, no claims have been allowed in the instant application. Applicants shall file terminal disclaimers as appropriate upon identification of allowable subject matter. Applicants invite the Examiner to telephone Applicants' undersigned representative at 215-665-5592 to arrange to have such terminal disclaimers transmitted to the USPTO by telefax upon such identification of allowable subject matter.

**Conclusion**

The claims are in allowable form. An indication that the claims are in condition for allowance is earnestly solicited.

Respectfully submitted,



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